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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,973	12/04/2000	Nick N. Nguyen	ASP-7	3999

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EXAMINER
CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/728,973	NGUYEN ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06/14/2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

MC

DETAILED ACTION

This non-final action is in response to the amendment received on 05/09/2005

Drawings

1. The drawings submitted on 06/14/2001are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Pages 7-8 of the specification recite that figure 1 includes the following elements: 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36 and 42. However, figure 1 refers to different element numbers. In addition, figure 5 includes element number 99. The specification does not mention such an element. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure submitted on 12/04/2000is objected to because of the following informalities:

On page 8, numbered lines 18-19, refers to element 56 in figure 2; however, such an element is not shown in figure 2. Also, page 9, numbered line 10, refers to element 86. Figures 3 and 4 do not includes element 86. Appropriate correction is required.

Claim Objections

3. Claim 16 is objected to because of the following informalities: in the amendment received on 05/09/2005, claim 16 depends on itself. Appropriate correction is required. In examining claim 16, the examiner assumed that it depends on claim 9.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 9, line 6, applicant recites the feature "admitting no carrier gas into the vaporizer"; however, the disclosure does not teach such a limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (EP 0 321 908).

With respect to claim 1, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1:1) including the following: an inlet (figure 2:20), an outlet (figure 1:13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13).

With respect to claims 2-3 and 6, the Hatanaka ('908) reference teaches the following: a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4, claim 5 (independently) and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908).

With respect to claim 4, the Hatanaka ('908) reference discloses an apparatus that includes a portion (figure 2, unlabeled space containing 9), which increases by at

least 70% or more when compared with for example, structure10 in figure 2. Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan. The Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) apparatus in order to achieve the desired mixing time.

With respect to claim 5, The Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (figure 1, 1) including the following: an inlet (figure 2, 20), an outlet (figure 1, 13), a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9) between the inlet (20) and the outlet (13), and a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) between the circuitous path (volume containing baffles 9) and the outlet (13) having an labeled inner orifice space connected to 10. Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus,

in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka circuitous path and the flow restrictor in order to achieve the desired mixing time.

With respect to claims 7-8, the restriction flow (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka reference recognizes the importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction in the Hatanaka apparatus in order to increase residence time of the sterilant and thereby achieve the desired mixing time.

12. Claims 9-12, 14-16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0 321 908).

With respect to claim 9, the Cummings reference teaches a method for hydrogen peroxide vapor sterilization in a chamber (col.1, lines 12-16) including the following: creating temperature (col.3, lines 61-63) and vacuum pressure (col.3, lines 21-23 and lines 29-30) conditions within the vaporizer to vaporize the sterilant (col.1, lines 32-35), admitting the sterilant in its liquid phase into the vaporizer (col.3, lines 30-32), admitting

no carrier gas into the vaporizer (the Cummings reference removes any air within the vaporizer and only injects hydrogen peroxide solution into the vaporizer), passing the sterilant in its vapor through a flow restriction (passage 20 in the figure due to its small diameter restricts the flow of the vapor going from the vaporizer 10 to the sterilization chamber 22) and passing the sterilant in its vapor phase out of the vaporizer (col.3, lines 36-46). However, the Cummings reference fails to teach passing the sterilant through a circuitous path. The Hatanaka ('908) reference teaches passing the sterilant through a circuitous path (in figure 2,the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 15-16, the Cummings reference discloses using liquid hydrogen peroxide (col.2, lines 51-53) such that water is a stabilizing compound for the liquid phase of the sterilant.

With respect to claims 10-12 and 14, the Cummings reference fails to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first direction through an inner tube positioned concentrically within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion

increases by at least 89% and having the sterilant make at least two turns each of which are at least 90 degrees. However, the Hatanaka ('908) reference discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 19-20, the Cummings reference fails to teach that the sterilant remains within the vaporizer for at least 17 milliseconds or for at least 26 milliseconds. With respect to claims 19-20, the restriction flow (figure 1, 9A) of the Hatanaka ('908) apparatus is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. The Hatanaka ('908) reference recognizes the

importance of achieving gas with a uniform density as a result of good mixing thereby residence time is based on mixing. In addition, residence time depends on the dimensions of the flow restriction. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the flow restriction of the Cummings reference in order to increase residence time of the sterilant and thereby achieve the desired mixing time as taught by the Hatanaka reference.

13. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0 321 908) in view of Hatanaka et al (U.S.P.N. 4,797,255).

With respect to claims 13 and 17, the Hatanaka ('908) reference teaches a method for providing a sterilant in the vapor phase (col.3, lines 24-58) including the following: creating temperature (figure 1:16) and pressure (the heated gas flowing into inlet 6 in figure 2, is intrinsically pressurized and col.3, lines 26-28) conditions within the vaporizer (figure 2:1), admitting the liquid sterilant to be vaporized (figure 2:20), passing the sterilant through a circuitous path (figure 2, is made up of the unlabeled volume containing 14 and baffles 9), then passing the sterilant through a flow restriction (figure 2, unlabeled space immediately above the entrance point to 10) and passing the sterilant out of the vaporizer (figure 1:13). Further, the cross-sectional area of the flow restriction (figure 2, 1, the unlabeled space immediately above the entrance point to 10 has a cross-sectional area) is no greater than about 25% of a cross-sectional area of the circuitous path immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the

cross-sectional area of the orifice is a matter of routine experimentation such that the Hatanaka ('908) reference recognizes the importance of achieving gas with a uniform density as a result of good mixing. The residence time is based on the desired mixing of the gases. Thus, in the absent of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dimensions of the Hatanaka ('908) circuitous path and the flow restrictor in order to achieve the desired mixing time. Regarding the disclosed percentage removal of the non-vaporizable components, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

With respect to claims 13 and 17, the Hatanaka ('908) reference fails to teach applying the vapor phase sterilant to a sterilization chamber. The Hatanaka ('255) reference discloses applying the vapor phase sterilant to a sterilization chamber (figure 4:1 and 29). Thus, it would have been obvious to one having ordinary skill in the art to at the time the invention was made to modify the method of Hatanaka ('908) reference to include a sterilization chamber as taught by the Hatanaka ('255) in order to sterilize packing articles independently of their forms with minimum consumption of hydrogen peroxide (col.1, lines 55-59).

With respect to claim 18, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

14. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301).

With respect to claims 1 and 5, the Hatanaka ('908) reference teaches an apparatus for vaporizing a sterilant (1) including the following: an inlet (20), an outlet (13), a circuitous path (9), creating temperature and pressure conditions to vaporize the sterilant (col.5, lines 28-35), passing the sterilant through a circuitous path (col.5, lines 35-57 and 9), and passing the sterilant out of the vaporizer (13). With respect to claims 1 and 5, the Hatanaka ('908) reference fails to teach the use of a flow restriction between the circuitous path and the outlet such that the flow restriction includes an orifice having a cross-sectional area no greater than 44.1% of a cross-sectional area of the circuitous path immediately upstream of the orifice. With respect to claims 1 and 5, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). Further, the Leibold reference teaches applying the vapor phase sterilant to a sterilization chamber (page 5, lines 13-14). Regarding, the cross-sectional area of the flow restriction (7 has a cross-sectional area) in the Leibold reference of being no greater than about 25% of a cross-sectional area of the circuitous path (9) immediately

upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation. As a result, it would have been obvious to one having ordinary skill in the art to modify the apparatus of the Hatanaka ('908) reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claims 2-3 and 6, the Hatanaka ('908) reference teaches the following: a plurality of baffles (9), the circuitous path includes an inner tube (10) positioned concentrically within an outer tube (figure 2, space containing 9), the circuitous path includes a first portion (unlabeled arrows in the space containing 9) and a second portion (figure 2, unlabeled arrows in 10), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled arrows in 14 and unlabeled arrows in space containing 9, and unlabeled arrows in 10).

With respect to claim 4, the Hatanaka ('908) reference teaches an apparatus that includes a portion (unlabeled space containing 9), which increases by at least 70% or more when compared with (10). Depending on the desired residence time within the apparatus, minimizing or maximizing such a region is well within the scope of the artisan since Hatanaka recognizes the importance of mixing the carrier gas with the disinfection gas is crucial to producing a gas with a uniform density (col.4, lines 6-16). Note that

mixing the gases involves time and this time interval is equivalent to the residence time of the gases within the apparatus.

With respect to claims 7-8, the flow restriction (7) in the apparatus of Leibold reference is intrinsically capable of retaining the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. On page 4, lines 1-9, the Leibold reference teaches that if a throttle or a nozzle or a valve is installed after the circuitous path and before the gas outlet of the vaporizer, then the speed of the emission of the vapor can be controlled. This statement means that depending on the intended use, if less flow rate of the vapor is desired to be emitted, then the flow restrictor will retain the vapor longer within the apparatus and the opposite is true.

15. Claims 9-12, 14,16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0321908) and further in view of Leibold (DE 2639301).

With respect to claim 9, the Cummings reference teaches a method for hydrogen peroxide vapor sterilization in a chamber (col.1, lines 12-16) including the following: creating temperature (col.3, lines 61-63) and vacuum pressure (col.3, lines 21-23 and lines 29-30) conditions within the vaporizer to vaporize the sterilant (col.1, lines 32-35), admitting the sterilant in its liquid phase into the vaporizer (col.3, lines 30-32), admitting no carrier gas into the vaporizer (the Cummings reference removes any air within the vaporizer and only injects hydrogen peroxide solution into the vaporizer) and passing the sterilant in its vapor phase out of the vaporizer (col.3, lines 36-46). However, the

Cummings reference fails to teach passing the sterilant through a circuitous path and passing the sterilant through a flow restriction. The Hatanaka ('908) reference teaches passing the sterilant through a circuitous path (in figure 2,the circuitous path is made up of the unlabeled volume containing 14 and baffles 9 as indicated by the arrows). As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claim 9, the Hatanaka ('908) reference fails to teach passing the sterilant through a flow restriction; however, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). As a result, it would have been obvious to one having ordinary skill in the art to modify the method of the Cummings reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claim 16, the Cummings reference discloses using liquid hydrogen peroxide (col.2, lines 51-53).

With respect to claims 10-12 and 14, the Cummings reference and the Leibold reference fail to teach the following: passing the sterilant past a plurality of baffles, passing the sterilant in a first direction through an inner tube positioned concentrically

within an outer tube, a second opposite direction between the inner tube and the outer tube, passing the sterilant through at least one portion in which an effective cross-sectional area of the portion increases by at least 89% and having the sterilant make at least two turns each of which are at least 90 degrees. However, the Hatanaka ('908) reference discloses the following: passing the sterilant past a plurality of baffles (figure 2, the unlabeled volume containing baffles 9), the circuitous path includes an inner tube (figure 2, unlabeled volume between 7 and outer walls of 10 and 11) positioned concentrically within an outer tube (figure 2, 2 and 3), the circuitous path includes a first portion (figure 2 that includes 14 where sterilant flows in downward direction between the inner tube and the outer tube 2 and 3) and a second portion (figure 2, volume through baffles 9 that the sterilant flows in an opposite direction), and the circuitous path includes two turns each are at least 90 degrees (figure 2, unlabeled downward flow direction of the sterilant and flow arrows through baffles 9). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a circuitous path as taught by the Hatanaka ('908) reference since such a path results in a gas having a uniform density for improved surface sterilization (col.4, lines 39-40) by preventing the disinfectant gas from forming into large drop (col.4, lines 9-13).

With respect to claims 19-20, the Cummings reference and the Hatanaka ('908) reference fail to teach that the sterilant remains within the vaporizer for at least 17 milliseconds or for at least 26 milliseconds. With respect to claims 19-20, the flow restriction (7) in the apparatus of Leibold reference is intrinsically capable of retaining

the vapor within the vaporizer to any desired time interval depending on the chosen parameters for residence time and for mixing time. On page 4, lines 1-9, the Leibold reference teaches that if a throttle or a nozzle or a valve is installed after the circuitous path and before the gas outlet of the vaporizer, then the speed of the emission of the vapor can be controlled. This statement means that depending on the intended use, if less flow rate of the vapor is desired to be emitted, then the flow restrictor will retain the vapor longer within the apparatus and the opposite is true. Thus, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of the Cummings reference by including a flow restriction as taught by the Leibold reference so that the speed of the emission of the vapor is controlled (page 4, lines 1-9).

16. Claim 15 is are rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings et al (U.S.P.N. 4,744,951) in view of Hatanaka (EP 0321908) and Leibold (DE 2639301) as applied to claim 9 and further in view of in view of Feasey et al (U.S.P.N. 5,130,053).

With respect to claim 15, the Cummings reference, the Hatanaka reference and the Leibold reference fail to explicitly teach adding stabilizing compounds to the liquid sterilants. However, the Feasey reference discloses adding stabilizing compounds to hydrogen peroxide (col.1, lines 5-8). Thus, it would have been obvious to one having ordinary skill in the art to modify the method of the Cummings reference to include stabilizing compounds as taught by the Feasey reference in order to decrease the rate

of decomposition of the hydrogen peroxide by contacting it with such compounds (col.3, lines 36-40).

17. Claims 13 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatanaka (EP 0321908) in view of Leibold (DE 2639301).

With respect to claims 13 and 17, the Hatanaka ('908) reference teaches a method (col.3, lines 24-58) and an apparatus for vaporizing a sterilant (1) including the following: an inlet (20), an outlet (13), a circuitous path (9), creating temperature and pressure conditions to vaporize the sterilant (col.5, lines 28-35), admitting the sterilant to be vaporized (col.6, lines 44-47, 20, and 14), passing the sterilant through a circuitous path (col.5, lines 35-57 and 9), and passing the sterilant out of the vaporizer (13). With respect to claims 13 and 17, the Hatanaka reference fails to teach the use of a flow restriction between the circuitous path and the outlet. In addition with regard to claims 13 and 17, the Hatanaka ('908) reference fails to teach applying the vapor phase sterilant to a sterilization chamber. With respect to claims 13 and 17, the Leibold reference teaches a flow restriction (7) between the circuitous path (2) and the outlet (6). Further, the Leibold reference teaches applying the vapor phase sterilant to a sterilization chamber (page 5, lines 13-14). Regarding, the cross-sectional area of the flow restriction (7 has a cross-sectional area) in the Leibold reference of being no greater than about 25% of a cross-sectional area of the circuitous path (9) immediately upstream of the orifice such that depending on the desired mixing and residence time within the apparatus, minimizing or maximizing the cross-sectional area of the orifice is a matter of routine experimentation. In addition, with regard to the disclosed percentage

removal of the non-vaporizable components, the Hatanaka reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

As a result, it would have been obvious to one having ordinary skill in the art to modify the method and apparatus of the Hatanaka reference to include a flow restriction between the circuitous path and the outlet as taught by the Leibold reference in order to allow the apparatus to be used continuously instead of only intermittently, in a controlled manner without danger to the surrounding and personnel (abstract, lines 13-15).

With respect to claim 18, the Hatanaka ('908) reference teaches using any means to remove non-vaporizable components (col.3, lines 15-18) prior to passing the sterilant out of the vaporizer. For example, a filter is intrinsically capable of removing any percentage of non-vaporizable components depending on the desired quality of the discharged vapor sterilant. Thus, determining the proper percentages removal is a matter of routine experimentation.

Response to Arguments

18. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

The Cummings et al reference (U.S.P.N. 4,744,951) is applied to show that a vapor phase sterilization system having a pressure below atmospheric pressure is known.

On page 7 of the Remarks section, applicant argues that, "Hatanaka et al. do not disclose a flow restriction between the baffle and the outlet." The examiner disagrees. The flow restriction in the Hatanaka ('908) reference is the unlabeled space immediately above the entrance point to the opening of inner tube 10 in figure 2.

On page 7 of the Remarks section, applicant argues that, "One of skill in the art would not be motivated to combine the teachings of Leibold with those of Hatanaka et al." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed.

On page 7 of the Remarks section, applicant argues that, "No throttle would be necessary to prevent surges and would be contraindicated as it would add an unnecessary pressure drop into the system thus reducing energy efficiency." The examiner disagrees. Adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed such that design modifications, i.e., pressure drop or other problems are a matter of routine experimentation that are within the scope of the artisan.

On page 7 of the Remarks section, applicant argues that, "As can be seen, such is not necessary when the rate is controlled by the rate of drops coming out of the

nozzle." The examiner disagrees. As mentioned above, adding the flow restrictor of the Leibold reference to the apparatus of the Hatanaka reference would result in the added advantage of increasing the precise control aspect of the amount of the sterilant dispensed so that any possible harm to surroundings or personnel is completely prevented. In addition, the flow restrictor of the Leibold reference gives the added advantage of storing the sterilant in case of interruptions in the supply source resulting in a continuous dispense of the sterilant.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JOHN KIM can be reached on (571) 272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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07/12/2005

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